

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of dietary approaches to stop hypertension (DASH) diet with regular hypocaloric diet on anthropometric indices, expression of some micro RNAs and genes involved in metabolic, inflammatory and hormonal status in obese adults

Protocol summary

Study aim

Comparison of the effect of dietary approaches to stop hypertension (DASH) diet with regular hypocaloric diet on anthropometric indices, expression of some micro RNAs and genes involved in metabolic, inflammatory and hormonal status in obese adults

Design

The controlled clinical trial with 3 parallel groups (40 in each group), double blinded, randomized by random number table method

Settings and conduct

The number of 120 (40 in each group) eligible patients having BMI more than 30 will be selected. Then the subjects will be divided into three groups by permuted block randomization. The three groups include: usual dietary recommendations, Hypocaloric diet, and DASH + Hypocaloric diet. The diet will be written to each individual. In this way, the required energy will be calculated based on Mifflin-St Jeor formula. In Group 1 the receiving diet including usual dietary recommendations without deduction of energy units. In Group 2 and 3 the rate of 500 kcal will be deducted, then units of each food groups will be determined based on a regular diet in group 2 and DASH diet in group 3. After 3 months of intervention, all groups will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients have BMI more than 30 and willing to participate in the study. Exclusion criteria: cardiovascular disease, liver disease, chronic diseases such as cancer, kidney failure; pregnancy; lactation; having certain diets like vegetarian and raw veganism; alcohol consumption.

Intervention groups

The subjects divide into 3 groups, Group 1: receiving diet including usual dietary recommendations. Group 2: receiving hypocaloric diet. Group 3: receiving hypocaloric

DASH diet

Main outcome variables

anthropometric indices; expression of some micro RNAs and genes involved in metabolic; inflammatory and hormonal status

General information

Reason for update

Acronym

DASHLOW

IRCT registration information

IRCT registration number: **IRCT20180712040438N5**

Registration date: **2020-07-12, 1399/04/22**

Registration timing: **prospective**

Last update: **2020-07-12, 1399/04/22**

Update count: **0**

Registration date

2020-07-12, 1399/04/22

Registrant information

Name

Jalal Moludi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 2148

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-25, 1399/05/04
Expected recruitment end date
 2020-10-22, 1399/08/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison of the effect of dietary approaches to stop hypertension (DASH) diet with regular hypocaloric diet on anthropometric indices, expression of some micro RNAs and genes involved in metabolic, inflammatory and hormonal status in obese adults

Public title
 The effect of dietary approaches to stop hypertension (DASH) diet on obesity

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Body mass index 35-25 kg /m 2 Age range from 20 to 50 years old
Exclusion criteria:
 Patients with severe diseases Pregnancy Alcohol consumption

Age
 From **20 years** old to **50 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
 Target sample size: **120**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Permuted block randomization method: First, the list of participants was provided according to their referral. Then all possible sequences that can be written with three groups, were written on paper (for 3 groups 12 sequences can be written). Then one of the numbers from 1 to 12 was considered for each sequence, for example for the ABC sequence 1 and for the ACB sequence 2 and as such, one of the numbers 3 to 6 was considered for the other 4 sequences. Then, using random number table, the random numbers were selected from one point to the left or right. Wherever the random number was 1 to 6, the corresponding sequence was recorded on the paper. This method continued until groups for the total number of participants were determined. Then, the names of subjects on the list were allocated to the specific groups according to the sequence of groups which had been determined by the

above mentioned procedure.
Blinding (investigator's opinion)
 Double blinded
Blinding description
 Participants, care giver and investigator are unaware of the differences in the incoming regimes.
Placebo
 Used
Assignment
 Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Faculty of Nutrition and Food Technology, Next to Farabi Hospital, Kermanshah, Iran , Postcode: 6719851552

City

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Approval date

2020-06-16, 1399/03/27

Ethics committee reference number

IR.KUMS.REC.1399.345

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Anthropometric indices

Timepoint

Baseline and End-of-trial

Method of measurement

Digital scale

2

Description

Blood sugar

Timepoint

Baseline and End-of-trial

Method of measurement

Automatic clinical chemical analysis device

3

Description

Lipid profile including TG, HDL-C, and TC

Timepoint

Baseline and End-of-trial

Method of measurement

Automatic clinical chemical analysis device

4

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Insulin

Secondary outcomes

1

Description

Adipokines levels include spixin, leptin, and adiponectin

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

ELISA

2

Description

Interleukin 6 and 10

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

ELISA

3

Description

hs-CRP

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

ELISA

4

Description

Expression of micro RNA 122a, mir15, mir155a, mir 146,

mir 193

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

RT-PCR

5

Description

PPAR γ Expression

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

RT-PCR

6

Description

FTO Expression

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

RT-PCR

7

Description

Bile acid (BA) profiles

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

Elisa

8

Description

LPS

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

ELISA

9

Description

Trimethylamine N-oxide

Timepoint

At the beginning of the study (before intervention) and three months after the beginning of the intervention

Method of measurement

ELISA

Intervention groups

1

Description

Control group: They will use a diet based on the Iranian

food pyramid and routine training that is normally provided by hospital nutrition experts.

Category

Placebo

2

Description

Intervention group: Receiving hypocaloric diet. In this group, the required energy of each person will be determined based on Mifflin-St Jeor formula, the rate of 500 kcal will be deducted then units of each food groups will be determined based on a regular diet.

Category

Treatment - Other

3

Description

Intervention group: Receiving dietary approaches to stop hypertension diet (DASH) hypocaloric diet. In this group, the required energy of each person will be determined based on Harris Benedict formula, the rate of 500 kcal will be deducted then units of each food groups will be determined based on DASH diet. DASH diet is rich in fruits, vegetables, whole grains, low-fat dairy foods and is limited in saturated fatty acids, total fat and cholesterol, refined cereals and sugar sweetened drinks with an overall 2400 mg per day sodium intake.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Medical Research & Training Hospital

Full name of responsible person

Dr. Jalal Moludi

Street address

Imam Reza Medical Research & Training Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research No 2 Central Building,
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farid_n32@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Jalal Moludi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data collected for the primary outcomes will be shared

When the data will become available and for how long

Accessibility to data is possible 8 months after publication.

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta analysis

From where data/document is obtainable

Dr Jalal Moludi, Faculty of Nutrition Sciences and Food Technology, Kermanshah University of Medical Sciences, +989399516766, j.moloudi@yahoo.com

What processes are involved for a request to access data/document

Any one who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All these steps will not take more than 10 days.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Jalal Moludi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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